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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,115	10/27/2006	Tomokaz Yoshinaga	0032-0292PUS1	2822

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EXAMINER

THOMAS, DAVID C

ART UNIT	PAPER NUMBER
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1637

NOTIFICATION DATE	DELIVERY MODE
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09/30/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/590,115	Applicant(s) YOSHINAGA ET AL.	
	Examiner DAVID C. THOMAS	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/27/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1-12 will be examined on the merits.

Specification

2. The abstract of the disclosure is objected to because it is not presented in narrative form and in a single paragraph. The abstract is also longer than 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite as it is written in multiple sentences such that multiple sets of limitations are presented. Furthermore, there are multiple grammatical errors in the claim, and there are two instances in which limitations are added parenthetically. Thus, it is not possible to determine what is distinctly claimed as the invention since it is not possible to determine the relationship of the limitations in different parts of the claim. See MPEP § 608.01(m) for proper form of the claims. Claims should contain only a period at the end. In addition, to assist in clarity, indentation should be used to set forth a plurality of elements or related steps.

In addition, a substrate is described in claim 1 in which a primer is hybridized to a template. Three alternate templates are set forth, 5'-NRWXZ-3', 5'-NRWX-3' and 5'-NRWXZY-3'. Primers are designated for the first two templates, but not for the third template, though Y is said to hybridize to X, suggesting a loop structure. However, it is not stated that Y represents the primer and therefore it is not clear that a primer is provided. The other parts of the substrate are also indefinite. N is designated as a 13-19mer of DNA, RNA or a chimeric nucleic acid, though in the only example describing a substrate in the specification, N = 0 (see Figure 1). R is described in the claim as RNA without any limitation to a particular length. Likewise, W is described as DNA or a chimeric nucleic acid of no particular length, and Z is described as DNA, RNA or a chimeric nucleic acid of no particular length. With regard to the limitations that include a chimeric nucleic acid, this term is defined in the specification as a nucleic acid constructed from DNA and RNA nucleotides (p. 9, line 30). However, the use of the term is inconsistent with claim 1 in that when X and Y are chimeric nucleic acids that hybridize with each other, they are described as being either both RNA or both DNA, not chimeric. Lastly, the final limitation of claim 1, appearing in parentheses, is "provided that, W and Z can be absent. It is not clear whether this limitation carries weight only when Z is present, or whether the presence or absence of W and Z depend on other regions of the substrate.

Finally, claim 1 contains no active step beyond incubating a reverse transcriptase with a substrate and metal ion, and adding a test substance and dNTPs to initiate DNA synthesis. It is not clear how an RNase H inhibitor is being screened by performing only

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the above named steps. Furthermore, it is not clear why the substrate containing RNA would not be cleaved by the RNase H activity of the reverse transcriptase prior to addition of dNTPs since it is known that such enzymes are capable of cleaving RNA in the template strand in the absence of DNA synthesis, as long as a metal ion is present (see p. 1, line 24 to p. 2, line 5 in the specification). Since the substrate described in claim 1 is a RNA:DNA heteroduplex, it would appear that the polymerization-independent RNase H activity of the enzyme would function to cleave the RNA before addition of dNTPs.

Allowable Subject Matter

5. Claims 1-12 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action. No prior art was found that teaches or suggests a method of screening for an RNase H inhibitor of a reverse transcriptase that comprises incubating a primer/template substrate comprising an RNA template and either a DNA or RNA primer with a reverse transcriptase in the presence of a metal ion, followed by adding and incubating a test substance with the mixture of the substrate, reverse transcriptase and metal ion, and then adding dNTPs to initiate DNA synthesis.

Conclusion

6. Claims 1-12 are rejected. No claims are allowable. However, the claims contain allowable subject matter, as discussed above.

Correspondence

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Thomas whose telephone number is 571-272-3320 and whose fax number is 571-273-3320. The examiner can normally be reached on 5 days, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David C Thomas/
Examiner, Art Unit 1637

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637